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| 09/802,686 | 03/09/2001 | Gary Van Nest | 377882000900 | 9981 |

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| EXAMINER | |
|---|---|
| LE, EMILY M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/802,686 | VAN NEST, GARY | |
| | Examiner | Art Unit | |
| | Emily Le | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03/20/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,8-10,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-10 and 16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Reassignment Affecting Application Location*

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

### *Status of Claim(s)*

2. Claims 6-7 and 11-15 are cancelled. Claims 16-17 are added. Claims 1-5, 8-10 and 16-17 are pending and under examination.

### *Information Disclosure Statement*

3. The information disclosure statement (IDS) submitted 03/22/2006 has been considered by the Examiner. However, since the publications retrieved from different internet sources and the international search reports are not true publications with a publication date, they are not fully in compliance with 37 CFR 1.97 and thus they will not be printed on the face of the patent issuing from this application.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 8-10 and 16-17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the enablement rejection set forth in the record, Applicant amended the claims and submits the following:

a) The "state of the art" factor alone is not enough to support a finding of non-enablement. Applicant further submits that Applicant's specification demonstrates that in the animal model described in the examples, intranasal administration of an ISS without administration of an RSV antigen, an immunostimulatory cytokine and an adjuvant results in the reduction of titer.

This submission has been considered, however, it is not sufficient to overcome the rejection. Applicant is reminded that the enablement rejection is made using factors summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)] for determining whether a disclosure would require undue experimentation. The factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In the instant, the enablement rejection is made in view of the factors provided above, and not solely in view of the state of the art.

Additionally, Applicant is reminded that the full scope of the claimed invention is directed at suppressing RSV infection, and not solely at the reduction of viral titer. The Office directs Applicant's attention to the definition provided in the specification for the

term "suppressing". The specification states that "suppressing" viral infection indicates any aspect of viral infection, such as viral replication, time course of infection, amount (titer) of virus, lesions, and/or one or more symptoms curtained, inhibited or reduced in an individual or a population of individuals treated with an ISS-containing polynucleotide in accordance with the invention as compared to an aspect of viral infection in an individual or population of individuals not treated in accordance of the invention. The specification continues by disclosing that a reduction of viral titer includes, but is not limited to, elimination of the virus from an infected site or individual. Thus, while the specification may demonstrate that the administration of an ISS without administration of an RSV antigen, an immunostimulatory cytokine and an adjuvant results in the reduction of titer, the specification has not demonstrated that the administration of an ISS to suppress viral infection.

b) The standard for compliance with section 112, first paragraph enablement is that the specification must adequately teach how to make and how to use the claimed invention, throughout its scope without undue experimentation. The standard for compliance with section 112, first paragraph enablement is not whether one of skill in the art would predict an outcome.

The submission has been considered, however, it is not sufficient to overcome the rejection. 35 C.F.R. § 112, 1st requires the specification to contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the

best mode contemplated by the inventor of carrying out his invention. And to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant, predictability is one of the eight factors considered in determining if the specification teaches the skilled artisan how to make and use the full scope of the claimed invention without undue experimentation. Thus, the predictability of an outcome does play a role in considering whether undue experimentation would be imposed on the skilled artisan.

c) The Examiner has not made a prima facie case of non-enablement based on the fact that he believes antigen needs to be co-administered with an ISS in order to induce an immune response. The claims recites a method of suppressing RSV infection, the claims do not recite "induction of a specific immune response".

The submission has been considered, however, it is not sufficient to overcome the rejection. While the claims do recite the phrase "suppressing RSV infection", however, the act of inducing a specific immune responses remains to be encompassed by the full scope of the claimed invention. The specific immune response to be induced by the claimed invention is a Th1 type response. Furthermore, it is well known in the art, at the time the invention was filed, that the extent in which an increase in Th1 activity impact infection is very much dependent on the presence of a disease specific antigen, as evidenced by Kobayashi. In the instant, no where in the specification has Applicant demonstrated that the administration of an ISS in the absence of a disease specific antigen is capable of suppressing infection, reducing viral load to the extent that results in the suppression of viral replication, reducing in the time course of infection, reducing in the number of lesions and/or one or more symptoms, or eliminating the virus from an infected site or individual.

d) Applicant submits that the test for enablement is not whether a certain amount of experimentation is required to practice an invention, but rather whether the amount of experimentation is "undue".

The submission has been considered, however, it is not sufficient to overcome the rejection. There are eight factors to be considered in determining whether a disclosure would require undue experimentation. One of which includes the quantity of experimentation required. In the instant, the Office considers the quantity of experimentation as one of the many burdens that would be required of the skilled artisan

practicing the claimed invention. And the presence of many burdens on the skilled artisan would necessarily lead to undue experimentation.

In the instant, the experimentation that the skilled artisan would have to conduct is beyond routine experimentation. As Fearon et al. demonstrates that the extent of immune stimulation induced by an ISS depends on the many factors, including the complete sequence of the ISS, the species in which the ISS is administered, and the length of the ISS. Thus, the issue here is not purely obtaining an optimal immune response. The issue here is that the skilled artisan would have to blindly experiment with the nucleic acid present in the ISS, the length of the ISS, and the species in which the ISS is administered in order to arrive at an ISS that is capable of providing the activity that is necessary for the claimed invention, suppression of RSV infection.

e) One of skill in the art would be able to determine an ISS that are optimized for human use.

This submission has been considered, however, it is not sufficient to overcome the rejection. In order for the skill artisan to determine an ISS optimized for human use, the skilled artisan would have to blindly experiment with the nucleic acid present in the ISS, the length of the ISS, and the species in which the ISS is administered in order to arrive at an ISS that is capable of providing the activity that is necessary for the claimed invention, suppression of RSV infection. And the presence of blind experimentation is a strong indicator that undue experimentation is involved.

f) Examples 1-2 demonstrate that an ISS that does not include a TCG element at the 5' end of the ISS reduced RSV titer in the animal model described when administered intranasally.

The submission has been considered, however, it is not sufficient to overcome the rejection. The Office recognizes that the ISS used by Applicant in examples 1-2 is capable of reducing RSV titer in the animal model in the absence of a TCG motif at the 5' end of the ISS. However, the art also teaches that a TCG motif at the 5' of the ISS is necessary for stimulation across multiple species. In the instant, Applicant has not demonstrated that the ISS used by Applicant is capable of providing stimulation across multiple species. Applicant has only demonstrated immune stimulation in one species.

In the instant, Applicant's specification teaches the use of an ISS lacking the TCG motif at the 5' end to induce an immune stimulation in rats. The art teaches that the TCG motif at the 5' end is necessary to induce an immune stimulation across multiple species. Applicant teaches one thing. The art teaches a different thing. The differences in the teachings validate the fact that the level and type of immune stimulation induced by a particular ISS does vary among each ISS, depending on the length of the sequence, the presence or absence of a TCG motif at the 5' end, the nucleic acids that flanks the ISS motif, and the species in which the ISS is administered.

g) Applicant submits that cotton rat is an acceptable model for RSV infection.

The submission has been considered, however, it is not sufficient to overcome the rejection. The issue here is truly due to the nature of the claimed invention, the use of ISS—which has been demonstrated to have different activities or intensity from one

species to the next, in cotton rat to demonstrate that the efficacy observed in the rats would transfer to other mammals. In the instant, Applicant has not demonstrated that the activities observed in cotton rats with the administration of ISS would transfer to other mammals.

h) Section 112 first paragraph, enablement, does not require that the claims be limited to "optimal" species.

The submission has been considered, however, it is not sufficient to overcome the rejection. The issue here is not limiting the claimed invention to an optimal species. The issue here, which has been repeatedly addressed by the Office, is the variability in ability of an ISS to stimulate an immune response, as evidenced by Silverman. Silverman teaches that different ISS have different activities in different mammals.

In all, as evidenced by the discussion provided above, and the complete analysis set forth in the previous office action, the Office finds that the specification is defective for it fail to teach the skilled artisan how to make and use the claimed invention without the burden of undue experimentation.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The rejection of claims 1-4, and 8-10 under 35 U.S.C. § 102(e) is withdrawn in view of Applicant's submission.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The rejection of claims 11-14 under 35 U.S.C § 103(a) over Davis is withdrawn in view of Applicant's cancellation of the claims.

***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-5, 8-10 and 16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of copending Application No. 10/898512. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant patent application is directed to a method of suppressing a respiratory syncytial virus (RSV) infection in an individual who has been exposed to RSV with the administration of a composition comprising an immunostimulatory sequence.

The conflicting patent application is directed to a method of reducing a symptom of a virus infection in an individual who has been exposed to a virus with the administration of a composition comprising an immunostimulatory sequence, wherein the sequence comprises a 5'-CG pyrimidine, pyrimidine, CG-3' motif.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application require the sequence comprises a 5'-CG pyrimidine, pyrimidine, CG-3' motif. However, this sequence is encompassed by the generic ISS sequence language that is recited in the broadest claim of the instant patent application.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not specify the virus in which the individual is infected. However, it is evident that by "viral infection", Applicant intends to encompass RSV infection. See paragraphs [0043-0044, and 0048] of the conflicting patent application's PreGrant publication, U.S. PreGrant Publication No. 20050059626.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application are specifically directed at the reducing the severity of the symptoms of a virus infection. However, it is noted that by the recitation "suppressing" viral infection, as recited in claim 1 of the instant patent Application, Applicant also intends to encompass the reducing the severity of the symptoms of a virus infection. See lines 3-16 on page 11 of the instant patent application. Specifically, at the cited passage, Applicant notes that "suppressing" viral infection indicates any aspect of viral infection, such as viral replication, time course of infection, amount (titer) of virus, lesions, and/or one or more symptoms curtained, inhibited or reduced in an individual or a population of individuals treated with an ISS-containing polynucleotide in accordance with the invention as compared to an aspect of

viral infection in an individual or population of individuals not treated in accordance of the invention. The specification continues by disclosing that a reduction of viral titer includes, but is not limited to, elimination of the virus from an infected site or individual.

The other notable difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not limit the length of the ISS sequence to greater than 6 and less than about 200 nucleotides in length. However, it is clear in specification of the conflicting patent application that by ISS, the sequence has to be greater than 6 nucleotides in length. See paragraph [0081 of the conflicting patent application's PreGrant publication, U.S. PreGrant Publication No. 20050059626.

The other notable difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not specify the individual to be a human. However, it is noted that by the recitation "individual", Applicant intended to encompass a human. See paragraph [0063] of the conflicting patent application's PreGrant publication, U.S. PreGrant Publication No. 20050059626.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not negate the administration of an immunostimulatory cytokine and an adjuvant with the administration of the ISS. However, it should be noted here that the claims the conflicting patent application does not require the co-administration of an immunostimulatory cytokine and an adjuvant with the administration of the ISS.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not require the administration to be at the nasal passages or at the lung. However, due to the nature of the virus, respiratory virus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to have targeted the nasal passages and lungs of individuals that are exposed or infected with a respiratory virus. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to treat the infection directly at the site of infection.

The last difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not require the ISS composition to comprise a modified phosphate backbone. However, at the time the invention was made, it is well known in the art that nucleic acid sequence having a phosphorothioate backbone is more resistant to nuclease degradation than nucleic acid sequence having natural phosphodiester backbone. Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the natural phosphodiester backbone of the nucleic acid sequence to a phosphorothioate backbone. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to extend the half-life of the nucleic acid sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-5, 8-10 and 16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of

copending Application No. 10/426237. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant patent application is directed to a method of suppressing a respiratory syncytial virus (RSV) infection in an individual who has been exposed to RSV with the administration of a composition comprising an immunostimulatory sequence.

The conflicting patent application is directed to a method of suppressing a respiratory virus infection in an individual who has been exposed to RSV with the administration of a composition comprising an immunostimulatory sequence, wherein the sequence comprises a 5'-CG-3' motif.

The notable difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not refer to RSV as the respiratory virus infection. However, it is noted that by the recitation "respiratory virus infection", Applicant intended to encompass RSV. See paragraph [0028] of the conflicting patent application's PreGrant publication, U.S. PreGrant Publication No. 20040009942.

The other notable difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not limit the length of the ISS sequence to greater than 6 and less than about 200 nucleotides in length. However, it is clear in specification of the conflicting patent application that by ISS, the sequence has to be greater than 6 nucleotides in length. See paragraph [0058] of the conflicting patent application's PreGrant publication, U.S. PreGrant Publication No. 20040009942.

The other notable difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not specify the individual to be a human. However, it is noted that by the recitation "individual", Applicant intended to encompass a human. See paragraph [0041] of the conflicting patent application's PreGrant publication, U.S. PreGrant Publication No. 20040009942.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not negate the administration of an immunostimulatory cytokine and an adjuvant with the administration of the ISS. However, it should be noted here that the claims the conflicting patent application does not require the co-administration of an immunostimulatory cytokine and an adjuvant with the administration of the ISS.

The difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application do not require the administration of the ISS composition to the lung. However, due to the nature of the virus, respiratory virus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to have targeted the lungs of individuals that are exposed or infected with a respiratory virus. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to treat the infection directly at the site of infection.

The last difference between the claims of the conflicting patent application and the claims of the instant patent application is: The claims of the conflicting patent application

do not require the ISS composition to comprise a modified phosphate backbone. However, at the time the invention was made, it is well known in the art that nucleic acid sequence having a phosphorothioate backbone is more resistant to nuclease degradation than nucleic acid sequence having natural phosphodiester backbone. Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the natural phosphodiester backbone of the nucleic acid sequence to a phosphorothioate backbone. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to extend the half-life of the nucleic acid sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The above double patenting rejection(s) is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this

use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

***Conclusion***

13. No claims are allowed.

14. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 03/22/2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
Art Unit 1648

E.Le
6/05/06